University of Alberta

A Bonding Study of Orthodontic Brackets Using Self Etching Primer

By

Helen Sonia Isabelle Grubisa

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Science in Orthodontics

Department of Dentistry

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Helen Sonia Isabelle Grubisa
3630 Cawthra Road
Mississauga, Ontario
L5A 2Y6

April 19, 2002

University of Alberta

Faculty of Graduate Studies and Research

The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled *A Bonding Study of Orthodontic Brackets Using Self Etching Primer* submitted by Helen Sonia Isabelle Grubisa in partial fulfillment of the requirements for the degree of Master of Science in Orthodontics.

Paul Major, Supervisor

Ken Glover

Giseon Heo

Don Raboud

M. Gary Faulkner

April 24/02

ABSTRACT

The purpose of this in-vitro study was to evaluate the shear bond strengths and inter-operator variability of self etching primer as compared to conventional phosphoric acid etching with 2 common orthodontic resins.

Two hundred and fourteen teeth were bonded using the following protocols. Group A: self-etching primer + Transbond XT light cure resin, Group B: 35% phosphoric acid + Transbond XT resin, Group C: 37% phosphoric acid + Enlight® bonding resin.

Teeth bonded with 35% phosphoric acid and Transbond XT resin demonstrated significantly higher bond strengths than the self etching primer ($p=0.004$), or phosphoric acid + Enlight ($p=0.002$) groups. There was no significant difference in mean shear bond strengths in the self-etching primer and the Enlight resin groups ($p=0.99$).

When 3 orthodontists bonded a total of 60 premolars using Group A and B protocols, mean bond strength values obtained were not significantly different between the 2 groups.

Dedication

This thesis is dedicated to my parents.

Your support and encouragement made it all possible.

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Thank you to my research committee members for your all your hard work, and advice. You have always been available to help me through the research process. I am grateful for your guidance.

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TABLE OF CONTENTS

Chapter 1: Literature Review		**Page**
1.1	Introduction	1
1.2	Statement of Problem	2
1.3	Research Questions	2
1.4	Literature Review	3
1.4.1	Enamel Etching and Bonding	3
1.4.2	Self Etching Primers	7
1.4.3.	Orthodontic Resin Bonding Studies	11
1.4.4	Study Design	12
1.4.5	Inter-operator Variability	15
Chapter 2: Paper for Submission to Publication		
2.1	Abstract	22
2.2	Introduction	23
2.3	Materials and Methods	25
2.4	Results	29
2.5	Discussion	33
2.6	Conclusion	38
Chapter 3	**Discussion**	
3.1	Study Design Limitations	41
3.2	Description of Stress vs. Time Curves	44
3.3	Self Etching Primer	44
3.4	Inter-Operator Variability	44
3.5	Recommendations for Future Study	45

Appendices....

Appendices

1	Human Research Ethic Board Approval	49
2	Supplemental Methodology Details	51
3	Tooth Allocation to Study Group Flow Chart	52
4	Material Lot Number and Expiry Date Information	53
5	Part A: Bond Strength Comparison Raw Data Values	54
6	Part B: Interoperator Variability Raw Data Values	58
7	Distribution of Shear Bond Strength Values	59
8	Curves of Stress vs. Time	60
9	Enamel Fracture Pictures	63

List of Tables

Table I	Shear Bond Strength by Study Group	Page	30
Table II	Enamel Fracture Rates by Study Group		30
Table III	Inter-Operator Variability in Shear Bond Strengths		31
Table IV	Inter-Operator Shear Bond Strength Significance Levels		31

List of Figures

Figure I	Testing Apparatus	Page	27
Figure II	Closer View of Testing Apparatus	Page	27
Figure III	Mean Bond Strength Values of 3 Orthodontists	Page	32

1.1 INTRODUCTION

In modern orthodontics, the ability to obtain a reliable adhesive bond to enamel without removing tooth structure, is often considered a given. Prior to enamel etching and composite resin bonding, a mechanical bond was the only available technique, requiring the banding of each tooth undergoing orthodontic treatment. This is not only time consuming and unattractive, but requires space closure after treatment completion.

Acid etching enamel to allow for adhesive bonding of filling materials is however, not a new concept. In 1955, Buonocore[1] introduced acid etching of enamel, and it has undergone many changes since then. Acids of differing types, concentrations, and exposure times have been used, both on enamel and dentin, for restorative as well as preventive, and orthodontics applications. What remained constant until fairly recently however, was the basic sequence of events required in composite resin bonding. The traditional sequence involves acid etching, followed by rinsing and drying, primer application, adhesive application, and finally composite resin application.

In an effort to simplify the technique, and to save time, manufacturers have introduced bonding "systems" in which 2 or more of the above steps are combined. The combination of priming and adhesive steps has been in clinical use for several years. Most recently, the combination of the acid etching, rinsing, and priming steps has been combined in a product called Transbond™ Plus. This product is manufactured by 3M Unitek® (Monrovia, USA), and is marketed for use in orthodontics.

For any "simplified" technique to be clinically viable, bonded orthodontic brackets must have adequate bond strength to prevent de-bonding prior to treatment completion, this bond strength must be achieved consistently, and the bond strength must not be too strong to prevent bracket removal after treatment completion.

1.2 STATEMENT OF PROBLEM

The recently introduced Transbond Plus™ self-etching primer has been recommended for bonding orthodontic brackets. Advantages suggested by the manufacturer include; ease of use, cost-effectiveness of one-step procedure, time efficiency, fluoride release and ability to work in both a dry and wet environment. The Transbond Plus Self Etching Primer does not require rinsing, so that contamination by saliva is minimized.

Decreased saliva contamination is in part because of elimination of the rinsing step, but also since less isolation time is required. In orthodontics, decreasing isolation time also translates into improved patient comfort.

The short time between product application and air burst, as well as the short air burst time, would imply a relatively "error proof" process. Technique sensitivity would be presumed small, as would the inter-operator variability.

For the advantages of the self etching primer to be valid, the material must provide a strong durable bond, which is comparable to conventional etching and bonding. This bond must also be achieved consistently.

1.3 RESEARCH QUESTIONS

1. To determine if the shear bond strength obtained using Transbond Plus Self Etching Primer is significantly different from that obtained using 37% phosphoric acid for enamel etching. Two commonly used light cure orthodontic resins; Transbond™ XT (3M Unitek®, Monrovia USA) and Ortho Enlight® (Ormco®, Orange USA) are used for comparison.
2. To determine the degree of variability in the bond strengths obtained in a sample using Transbond Plus Self Etching Primer for enamel preparation.
3. To determine the inter-operator variability between 3 orthodontists using the one step Transbond Plus Self Etching Primer for enamel preparation.
4. To compare inter-operator variability with Transbond Plus Self Etching Primer to the inter-operator variability using the conventional phosphoric acid etching technique.

Hypotheses:

1. Shear bond strengths obtained using Transbond Plus Self Etching Primer are not significantly different from those obtained using conventional phosphoric acid etching.
2. Variability in bond strengths with Transbond Plus Self Etching Primer is less than the variability using conventional phosphoric acid etching.
3. Inter-operator variability with Transbond Plus Self Etching Primer, is less than that of conventional etching.

1.4 LITERATURE REVIEW

1.4.1 ENAMEL ETCHING AND BONDING

In a clinical setting, the failure of an orthodontic bracket to remain bonded for the duration of treatment not only is an inconvenience for the patient, but also requires chair time to re-bond and may prolong overall treatment time if bracket de-bonding occurs frequently.

Different practitioners and offices have differing bond failure rates, and many offices track this information. Anecdotally, failure rates range from 1-10%, however, relatively few references to clinical bond failure rates exist in the literature. A randomized clinical trial done by Sunna and Rock (1998) to compare the clinical performance of uncoated and pre-coated adhesive brackets (using Transbond XT, as in the current study) found an overall bond failure rate of 6.6% over a period of one year[2]. Previous studies comparing light cure to chemical cure resins have shown bond failure rates of 4.7-6.0%[3], 4.5-7.7%[4], and most recently, 11.3-12%[5].

Given the number of steps in the bonding of an orthodontic bracket, there are numerous variables contributing to improved or diminished bond success. Each step in the chain must be successful, providing a link to the next. The first step, the successful etching of the enamel surface, is thus paramount. The way in which enamel is etched has

undergone many changes in both materials and technique since Buonocore[1] suggested it. Various acids have been used at different concentrations, with different etching times, in the hope of achieving bond success in a minimum of time. The introduction of a self-etching primer is the most recent modification to the etching process.

The techniques and materials used to etch enamel are only half of the equation. The tooth surface, or enamel, is not constant in all patients. The exposure of teeth to fluoride during their development is well known to decrease both caries, and bonding success rates by decreasing the solubility of enamel[6 7]. The surface structure of enamel also varies according to the location within the dental arch.

A... REVIEW OF ACID ETCHING

Enamel, without conditioning, is a poor substrate for bonding, since it is porous, covered by an organic pellicle (over an inorganic substrate), not smooth, and has low surface reactivity in the mouth[8]. Treating the enamel surface with acid, was recognized as a method of increasing this surface energy. The acid etching serves to dissolve old and fully reacted enamel, as well as removing the residual pellicle and smear layer to expose the inorganic crystallite component of enamel[9]. The porosity of enamel is increased with enamel etching, with the discrete dissolution of enamel rods, and an increased surface area results[10]. This increased wettability of enamel after etching makes the penetration of the polymerizing resin possible, and when cured, the resin tags will provide a mechanical bond to the enamel[11].

The depth of etch achieved and the amount of surface enamel removed, is dependent on the type and concentration of acid used[12].

B... VARIOUS ACID ETCHANTS

The gold standard for enamel etching is phosphoric acid. It is the most widely used and accepted for comparison, at a concentration of 30-40% (see 1.4-C) especially in orthodontics.

Numerous other acids have been proposed for enamel etching, including citric, oxalic, maleic, and nitric acid. Nitric acid at 2.5% by weight (w/w) is commercially available for restorative purposes, and its acid etch pattern on extracted premolars has

been examined with scanning electron microscopy[13]. The 2.5% nitric acid was found to be significantly less effective at etching enamel than 37% w/w phosphoric acid (15, 30, 60 seconds) when applied to the orthodontic bonding surface of mandibular premolars.

However, the results of an in-vitro bonding study showed no significant differences in the bond strength obtained between ceramic brackets bonded to the 2.5% nitric acid etched teeth, to those etched with 37% phosphoric acid[14].

C... PHOSPHORIC ACID CONCENTRATION EFFECTS

While Buonocore first used phosphoric acid at a concentration of 85%[1], this has progressively decreased so that commercially available formulations now range from 30-40%.

Scanning electron microscopic examination of enamel etched with phosphoric acid concentrations of 35%, 20%, 10% and 5%, showed that with etching times less than 30 seconds, the difference in loss of enamel structure is not significantly different, with a value of approximately 5μm[15]. With etching times greater than 30 seconds, there was a linear increase in the loss of enamel with increasing acid concentration. The SEM investigation showed that etch patterns were gradually more pronounced with increased etch duration and acidity, however, no significant differences were found in shear bond strengths[15].

D... ETCH TIME EFFECTS

An in-vitro study comparing the shear bond strengths of various orthodontic adhesive systems using 15 seconds versus 60 seconds of etch time, showed no significant differences between the 2 etch times[16] within one bonding material.

This finding is contrary to that of Orsorio et al, where extracted human premolars treated with 60 seconds of 37% phosphoric acid showed significantly higher bond strengths than those etched for 15 seconds[17]. However, the authors also state that while the groups differ statistically, both etch times produced bond strengths greater than that required for successful bonding.

A scanning electron microscopy study using extracted premolars demonstrated that when 37% phosphoric acid etch times of 15, 30, and 60 seconds were compared, the

quantity of "good" quality etch was time specific; 15 seconds being significantly less effective than 30 or 60 seconds [13]. No significant differences were found in the occlusal half of the orthodontic bonding area as compared to the gingival half, for any acid application time[13].

Several clinical trials, and in-vivo studies examining the effects of decreased etch time have been done [18-20].

An in-vivo study by Sadowsky et al. involved the bonding of orthodontic attachments to teeth having been treated with either 15 seconds or 60 seconds of 37 % phosphoric acid. Teeth in contra-lateral quadrants, (same patient) served as the comparison groups, and the clinical failure rates after 15-24 months of treatment were found to be the same for both 15 and 60 second etch times[18].

Carstensen et al. also followed the clinical results of brackets bonded on enamel having had 15-20 seconds, or 30-35 seconds of 37% phosphoric acid etch exposure[20]. Comparison groups were bonded teeth on the left and right sides of the patient's dentition, and after 9 months of treatment, there was no significant difference between them, suggesting that the 15 second etch time is sufficient for clinical use[20]. This finding is confirmed in a clinical study by Kinch et al, which found no difference in bond failure rates, or bond survival times for teeth bonded after 15 or 60 seconds with 37% phosphoric acid[19].

E... EFFECTS OF TOOTH TYPE

Tooth type (incisor, molar) has a significant effect on bond strength. Hobson et al.[21] found that when various extracted human teeth were bonded using stainless steel brackets and composite resin, the shear bond strengths differed greatly depending on the tooth's location in the mouth. The highest mean shear bond strength was on the lower first molar teeth, while the lowest were found on maxillary first molars. Maxillary anterior teeth had larger bond strengths than maxillary posterior teeth, with the reverse being true in the mandible. Premolar bond strengths were similar for maxillary and mandibular teeth, but significant differences were found between maxillary and mandibular second premolars, with maxillary second premolars having significantly lower bond strengths[21].

A clinical trial also found that bond failure rates depended highly on tooth position, with second premolars showing the highest rate of bond failure[19]. The premolars showed variable patterns of bond failure, depending on the quadrant, and the etching time used.

1.4.2 SELF-ETCHING PRIMERS

Self-etching primers serve as both dental surface conditioner (etch), and primer, without the need for rinsing before adhesive placement. Self-etching primers are acidic monomers, and the rationale for their use is the formation of a "continuum" between the tooth surface and the adhesive material by the simultaneous demineralization and resin penetration with acidic molecules [22]. The depth of the enamel demineralization and bonding agent penetration are identical since both processes occur in concert[23]. The light curing of the penetrated monomers, and their copolymerization with the overlying composite resin forms this continuous bond with the enamel surface[23].

Self-etching primers for used on dentin have been in use for some time, and scanning electron microscopy studies have shown them capable of producing a successful hybrid layer in dentin with various bonding adhesives[24 25]. Numerous in-vitro dentin bonding studies have also shown good adhesion with self-etching primers in combination with various restorative materials such as composite and glass ionomer[26-29].

In restorative dentistry, systems are available with self-etching primer for use on both dentin and enamel. Because of the ultra-structural and organic content differences between enamel and dentin, these self-etching primers have not always shown adequate bond strengths in both substrates[30].

A newer generation product consists of a self-etching primer for use solely on enamel. Again, this was used in restorative dentistry first, and a new product has recently been introduced for use with orthodontic attachments.

A... SELF-ETCHING PRIMERS IN RESTORATIVE DENTISTRY

A 1999 shear bond strength study on bovine enamel showed that of 4 adhesive systems, the one containing self-etching primer (Etch & Prime 3.0) yielded significantly lower bond strengths[31]. The self-etching primer used in the study contained HEMA (2-

hydroxyethyl methacrylate) and tetra-methacriloxy-ethypyrophosphate, as catalysts, with HEMA, ethanol and water as carriers. The function of solvents such as acetone and ethanol is residual moisture removal to enhance the resin wetting of the etched enamel

Another self-etching primer, LB-Primer (Kuraray Co. Japan), was studied to evaluate the shear bond strengths and compare them with scanning electron microscopy morphology[32]. This self-etching primer (part of the Clearfil Bond System) contains Phenyl-P, HEMA, and 5-NMSA in ethanol and water, with the Phenyl-P being a slightly acidic phosphonated molecule. Extracted human molars were used in the study, and the depth and pattern of enamel etch of the self-etching primer was compared to that of phosphoric, maleic, and nitric acids. The self-etching primer provided significantly shallower enamel etch, perhaps due to poor penetration of the self-etching primer into the enamel microporosities, or to calcium precipitation on the enamel surface, masking the etch pattern and interfering with resin penetration[33]. Although self etching primer enamel etch depth was less than with other acids, no significant differences were found in the mean enamel shear bond strengths.

Pashley and Tay[34] compared the effects of 3 self-etching primers (Clearfil Mega Bond (Kuraray), Non-Rinse Conditioner (Dentsply DeTrey) and Prompt L-Pop (ESPCE)) on the unground enamel surfaces of extracted human bicuspids. Both the ultrastructural features (scanning electron microscopy), and tensile bond strengths using the 3 self-etching primers were examined, as compared to a control of 32% phosphoric acid gel. The etching pattern (as seen by scanning electron microscopy) varied among the three groups, with Clearfil Mega Bond resulting in the mildest etching patterns, and Prompt L-Pop producing an etching effect that approached that of the phosphoric acid control, with an overall increase in microporosity evident along the entire aprismatic enamel surface. The L-Prompt also produced a substance hybrid layer that was as thick as 4μm, or 3 times as thick as the other 2 products.

When the tensile bond strengths of the 3 groups (using their corresponding composite resin) were compared, they were all significantly lower than that of the control group, with no difference between the 3 self-etching primer groups found. To assess only the self-etching primer effects, a standard composite resin was substituted for all groups

and the tensile bond strengths achieved with Prompt L-Pop and Non-Rinse Conditioner were not different from the control group[34].

Non-Rinse Conditioner (DeTrey) has also been suggested for use in orthodontics by Dyract Orthodontics to allow enamel etching prior to bracket placement, without rinsing[35]. A scanning electron microscopy study of the acid etch pattern obtained with Non-Rinse Conditioner (NRC), found that with 20 second exposure, NRC produced an etch pattern that was less destructive to the unground (human) enamel, but that the retentive patterns of acid etch associated with phosphoric acid were absent[35]. The authors suggest that the uniform porosity and generalized pitting associated with NRC etching would however, be a potentially retentive surface.

Another in-vitro study compared 3 self-etching primers (LB Primer (Kuraray), Etch & Prime 3.0 (Degussa), and Resulcin AquaPrime (Merz)) to 37% phosphoric acid with respect to scanning electron morphology and shear bond strength[23]. The bond strengths of composite resin to bovine enamel attainted by the 3 self-etching primers (and their respective composite resin) were not significantly lower than those attained by the conventional acid-etch technique, with AquaPrime instead being significantly higher.

B... DRYING TIMES EFFECTS ON SELF-ETCHING PRIMERS

When using self-etching primers, there is no need for rinsing, however, these materials do need to be air dried. This air drying is to eliminate solvents such as water, acetone or ethanol. Manufacturer's instructions of "air blow gently" allow for different times of air drying, depending on the operator.

Miyazaki et al. used 3 self-etching primer systems (Fluoro Bond (Shofu), Liner Bond II (Kuraray), and Mac Bond (Tokuyama)) on bovine incisors, with varying drying times of 0, 2, 5, 10, 20, and 30 seconds[36]. Air drying times had a significant effect, with weaker shear bond strengths obtained at shorter drying times for all systems. Furthermore, not all self-etching primers were equally sensitive to this loss of bond strength with decreased drying time.

The etch morphology achieved with different drying times was also examined in the Miyazaki et al. study. Resin tag penetration was not clearly seen when the self-

etching primer was not air dried, compared to intimately adapted resin tags being visible at 30 seconds of drying[36]

C... SELF-ETCHING PRIMERS FOR ORTHODONTIC USE

The L-Prompt L-Pop self-etching primer introduced by ESPCE America (Plymouth, USA) in early 2000 was proposed for use with all resin based composites, on enamel and dentin. In late 2000, 3M Unitek (Monrovia, USA) introduced the *Transbond Plus Self-Etching Primer*, which is another brand name for the L-Pop system[37]. The system consists of a blister foil with 3 bubbles, for use in one patient only.

The Transbond Plus material safety data sheet lists methacrylated phosphoric acid esters as the main ingredient, no volatile organic compound content, and a material pH of 1.0[38].

The mechanism of action of Transbond Plus as described by Cinader[39] (3M publication) is as follows:

> "The phosphate group of the methacrylated phosphoric acid ester dissolves the calcium and removes it from the hydroxyappatite. Rather than being rinsed away, the calcium forms a complex with the phosphate group and is incorporated into the network when the primer polymerizes. In this manner the acid is neutralized"

Two in-vitro studies have been done to examine the shear bond strengths obtained using self-etching primers for orthodontic attachment bonding[40 41].

In 1998, Bishara et al. compared the shear bond strengths achieved using an acidic primer (containing Phenyl-P and HEMA), as compared to teeth treated with 10% maleic and 37% phosphoric acids, when bonding orthodontic brackets to extracted human molars[40]. Clinically acceptable shear bond strengths (10.4±4.4 MPa) were found when a highly filled (77%) adhesive was used, comparable to those achieved with phosphoric acid etching (11.8±4.1 MPa). When a lightly filled (10%) resin was used with the acidic primer, the bond strengths were significantly lower (5.9±5.6Mpa)[40]. The type of adhesive used with the acidic primer is thus clinically relevant.

In the same study, photomicrographs of the resin interface of a tooth etched with the acidic primer showed differences from that of a tooth etched with a phosphoric acid. The resin tags with phosphoric acid etch are thick and uniform, while those of the acidic

primer were thin, and less uniform. The authors hypothesize that this might account for the observation that less resin remains adhered to the tooth after debonding when a tooth is conditioned with an acidic primer[40].

Most recently, L-Prompt self-etching primer was studied by Bishara et al, to assess the shear bond strengths achieved when bonding orthodontic brackets to extracted human molars[41]. The exposure time for the L-Prompt was 20 seconds, as per manufacturer's (ESPE) instructions, and the control group used 37% phosphoric acid. Both groups used the same (Transbond XT) bonding resin. Results showed mean shear bonds strengths of 7.1±4.4 MPa for the self-etching primer group, as compared to 10.4±2.8 MPa for the control. The lower bond strengths achieved with the L-Prompt were statistically significant, but the mean of 7.1 MPa is clinically acceptable according to the authors[41].

1.4.3 ORTHODONTIC BONDING RESIN STUDIES

Given the variety of bonding systems available for orthodontics, the literature contains many studies comparing them, both in-vitro, and in a clinical setting. In the interest of brevity, only more recent, light cure resin focussed studies will be included.

Twenty-two orthodontic bonding adhesives (light and chemical cure) were compared in a 1997 study by Willems et al. using extracted human premolar teeth and 37% phosphoric acid etch time of 60 seconds for all groups[42]. The resulting shear bond strengths ranged from 4.1±0.8 MPa for Heliosit (light cure)9.9 MPa±1.5 MPa for Concise (chemical cure), with a Transbond XT value of 8.4±0.8 MPA. The statistical interpretation of these results is limited given the small number of teeth per group (twelve) but it provides a good overview of the variety of values obtained with different bonding systems.

Three light cured orthodontic adhesives, Transbond XT, Enlight, and RMGIC were compared in-vitro using 70 extracted premolars by Owens et al[43]. Thirty-seven percent phosphoric acid etch for 30 seconds was used for all groups, followed by unfilled resin placement, light curing, and adhesive loaded bracket placement. There was no significant difference between the 2 composite groups, with values of 7.9±2.1 for

Transbond XT, and 6.8±2.1 for Enlight, but the glass ionomer cement yielded significantly lower shear bond strengths (5.3±1.2).

1.4.4 STUDY DESIGN

A. FINITE ELEMENT MODEL ANALYSIS AND REPORTING OF DATA

A finite element model (FEM) can be used to analyse the stresses generated at a bracket-cement-tooth interface. This mathematical model has been proposed as a more precise evaluation of the orthodontic attachment than in-vitro bonding studies, since the quality of an orthodontic attachment is primarily determined by these stresses[44]. According to Knox et al., finite element models are ideally suited to providing insight into the structural behaviour of the stresses generated in response to an applied load on an orthodontic attachment[44].

Knox et al. constructed 2 and 3-dimensional finite element models of the bracket-cement-tooth system, to evaluate the effects of the physical properties and geometry of the cement when a tensile force is applied[44]. Variations in lute thickness between 0.175 and 0.375 mm had little influence on the major principal stresses. However, as cement thickness increased, the principle stresses changed, and increased stresses were recorded at the lute periphery.

A finite element model was used by Katona to compare the stresses generated at the orthodontic attachment when different types of applied forces were used[45]. Force types studied were tensile, shear/peel, and torsion with generated stresses varying greatly by system. Because of the different stresses generated at the bond interface, the values reported for torsional bonding studies cannot be compared to those using tensile or shear/peel. Variables that are frequently neglected in bonding studies include bond thickness and uniformity, location and method of force application, alignment of the specimen, and the force. As per Katona, since these variables affect test results, comparisons are difficult[45].

B... SURFACE ROUGHNESS TREATMENT

The surface to be etched for bracket bonding is intact enamel, unlike the prepared enamel (and dentin) in restorative preparations. Several studies have be done to assess if

"preparing" this intact enamel might improve the bond strength[46 47]. When enamel surfaces were ground flat using a variety of rotary instruments (in vitro), there was no significant difference in the shear bond strengths achieved with grinding, without grinding, or between different grinding groups [46].

While grinding away enamel is not a feasible option, the preparation of the enamel by air-powder polish is. When the tensile bond strengths of teeth treated with air-powder polish were compared with those prepared with pumice and prophy cup, no significant difference was found[47].

Since neither the literature, nor common practice suggests a need for enamel surface "roughening", it was not included in the study.

C... PUMICE PROPHYLAXIS

It is widely accepted that enamel surfaces must undergo a prophylaxis with pumice prior to orthodontic bonding to achieve good enamel etching. As such, most orthodontic offices do pumice the teeth prior to bracket bonding. Manufacturers concur, including the pumice prophylaxis step in their instructions, as do both the manufacturers in the present study (3M Unitek and Ormco). For this reason, the study design included 10 seconds of pumice prophylaxis prior to bonding.

In the literature, recent studies have not supported the need for this step[48 49]. A clinical study of 614 directly bonded brackets showed no statistically different failure rates (maximum 16 months treatment) in groups having, or having not had pumice prophylaxis prior to bondin[48]. In an associated in vitro study, shear bond strength testing was performed on extracted premolars to compare those having undergone pre-treatment with pumice prophylaxis, and those which had not[49]. There was no statistically significant difference in the bond strengths achieved. The same study used scanning electron microscopy to examine the acid etch pattern obtained with phosphoric acid etching, and again, there was no significant difference in the etched enamel surface characteristics in teeth which had, and had not been prophylaxed with pumice[49].

An older study however, contradicts these findings. A 1973 study demonstrated that bond strengths were increased by 50% with a pumice prophylaxis prior to bonding [50].

D... THERMOCYCLING

Initial bond strength of a composite resin is very important, but is only part of the equation, since resin bonds are expected to last for a significant period of time. The durability of the resin bond intraorally is essential for long-term clinical success. Thermocycling is the laboratory attempt to simulate the temperature changes which occur in vivo.

The thermocycling protocol (cycles and temperatures) used in this study was taken from that of Lee-Knight et al[51]. While many composite bonding studies omit thermocycling in their study design[40 41 46 47 52 53], others studies use variety of protocols ranging from 100 cycles[16] to 500 cycles[32] up to 2500 cycles[23].

A review of thermocycling procedures being used in laboratory restorative material testing was done by Gale and Darvell[54]. They confirm the wide variation, and contradictory results, making comparison of protocols difficult. They conclude that there is a value to thermal stressing only when the initial bond is known to be reliable. The authors' proposed standard cyclic regimen is 35°C (28 sec), 15°C (2 sec), 35°C (28 sec), 45°c (2 sec) with a provisional estimate of 10,000 cycles representing one year of in-vivo exposure[54].

Different materials may vary in their susceptibility to thermocycling effects, and the thermocycling duration. When the shear bond strengths of orthodontic brackets (light cure, phosphoric acid etch) subjected to 580 cycles of thermocycling (55°C ± 2° and 10°C ± 2°, 60s each) were compared to controls, no significant difference was found[55]. Miyazaki et al[56] examined the effect of thermal cycling (5°C/ 60°C for 3,000, 10,000 and 30,000 cycles) on the enamel bond strength of self-etching primer and self-priming adhesive systems. Thermal cycling caused a significant decrease in bond strength for the self-etching primer system, whereas the self-priming systems did not show any significant differences. As well, the mean enamel bond strengths decreased as the number of thermal cycles increased.

E... TIME TO SHEAR BOND TESTING

The time interval between bonding of an orthodontic attachment, and shear bond strength testing varies among published studies from several hours to a week. When

thermal cycling is done, this lengthens the time interval, regardless of the temperatures involved.

Bishara et al[57] examined the effect of time on the bond strengths of glass ionomer and composite orthodontic adhesives. Bond strengths were assessed within 30 minutes, and at 24 hours, with the shorter interval representing the elapsed time at an orthodontic bonding appointment prior to archwire engagement. The composite adhesive had significantly stronger initial bond strength, that doubled within the first 24 hours, while the glass ionomer values were significantly lower, but increased 20-fold over the 24 hour period.

F... CROSSHEAD SPEED

The testing apparatus used for shear bond strengths consists a bonded bracket (or resin bead, to which a force is applied parallel to the resin-tooth interface. The force application is carried out by a crosshead (rod) which descends at a fixed speed, increasing the force application until the resin separates from the tooth surface.

Shear bond strength studies of bonded orthodontic attachments use a variety of crosshead speeds. Commonly used values are 0.1mm/min[42 43], 0.5mm/min [31 58], 1mm/min[23], and 5mm/min[32 40 55], as well as several in between.

1.4.5 INTER-OPERATOR VARIABILITY

There are limited references in the literature regarding the inter-operator variability existing among dentists. Most references do however, pertain to bonding of restorative resins.

When fissure sealants placed by 2 different operators, were examined at regular recalls, the inter-operator difference in retention rates was as much as 24% at 3 year recall[59]. Initial placement technique was the suggested reason for the inter-operator difference, which remained almost constant at each recall visit

A wide variety of restoration margin quality resulted when five practicing general dentists were asked to place composite resin restorations in extracted teeth (standard dentinal preparation) using a one-bottle adhesive, having been provided with the manufacturers instructions only[33]. It was noted by the study authors that not all the

operators read the instructions fully, and that some did not concentrate on the procedure at hand. The authors suggest that dentists are sometimes unaware that basic application principles may change with the introduction of new generation (less steps, "simpler") bonding materials.

Another inter-operator study compared dental students and dentists with varying clinical experience in their ability to use a new dentin adhesion system [60]. The 24 operators were asked to bond bovine dentin (standard preparations) after having watched a demonstration, with the outcome measure being the resulting bond strengths. Wide deviations in mean tensile bond strength were noted among operators, irrespective of clinical experience, or student/dentist status. No correlations could be made with respect to clinical experience and bond strengths achieved.

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CHAPTER 2: Research Paper

2.1 ABSTRACT

The bonding of orthodontic brackets to enamel is a multi-step technique. To simplify bonding and decrease chair time, Transbond™ Plus Self Etching Primer (3M Unitek®) has been introduced, combining the etching, rinsing, and priming steps.

The purpose of this in-vitro study was to evaluate the shear bond strengths and inter-operator variability of self etching primer as compared to conventional phosphoric acid etching with 2 common orthodontic resins.

Two hundred and fourteen teeth were bonded using the following protocols. Group A: self-etching primer + Transbond XT light cure resin, Group B: 35% phosphoric acid (15 sec) + Transbond XT resin, Group C: 37% phosphoric acid (15 sec) + Enlight® bonding resin.

Results demonstrated significantly higher bond strengths when teeth were bonded with 35% phosphoric acid and Transbond XT resin, than with the self etching primer ($p=0.004$), or phosphoric acid + Enlight ($p=0.002$) groups. The mean shear bond strengths of the self-etching primer group were not significantly different than those etched with 37% phosphoric acid + Enlight resin ($p=0.99$).

When 3 orthodontists bonded a total of 60 premolars using Group A and B protocols, significant differences in shear bond strengths and strength ranking, were found. The mean values obtained by the 3 operators using the self etching primer were not significantly different, while significant differences in mean values were found between operators when phosphoric acid etch technique was used.

2.2 INTRODUCTION

In orthodontic practice, the ability to obtain a reliable adhesive bond between an orthodontic attachment and enamel is essential. The interface must allow the transmission of forces from the archwire to the tooth, as well as withstand the forces of mastication without failing, for the duration of orthodontic treatment. In a clinical setting, the failure of an orthodontic bracket to remain bonded is not only costly, but is an inconvenience for the patient, and prolongs treatment time.

The multi-step bonding process has until recently, always included the conditioning of the enamel surface by an acid prior to the primer and adhesive placement. Acids of differing types, concentrations, and exposure times have been used since Buonocore[1], and today phosphoric acid in the concentration of 30-40% remains the most common for orthodontic applications.

In an effort to simplify orthodontic bonding and to save chair time, materials that combine two or more steps have been manufactured. In late 2000, 3M Unitek® (Monrovia, USA) introduced Transbond™ Plus Self Etching Primer, which combines the acid etch, rinsing, and priming steps into one. Previously known as Prompt L-Pop (ESPE America, Plymouth USA), it comes in a single use foil package, containing 3 bubbles that are pressed and folded to combine the ingredients before use.

Once activated, the foil pack contains an applicator to rub the material on the enamel surface for 3 seconds, followed by a 1-2 second air burst. No rinsing is required after application, and the tooth is ready for bracket placement.

In 1998, Bishara et al.[2] compared the in-vitro shear bond strengths achieved using an acidic primer (containing Phenyl-P and HEMA), compared to teeth treated with other acids, when bonding orthodontic brackets. The self etching primer group had clinically acceptable shear bond strengths (10.4±4.4 MPa), comparable to the 37% phosphoric acid group (11.8±4.1 MPa) when a highly filled resin was used, but significantly lower (5.9±5.6MPa) strengths resulted with a lightly filled (10%) resin[2].

In the same study, photomicrographs of the resin interface showed that with phosphoric acid, resin tags were thick and uniform, compared to thin and less uniform with the acidic primer[2]. Furthermore, when a tooth was conditioned with acidic primer, less resin remained adhered after debonding.

Prompt L-Pop self-etching primer was studied by Bishara et al.[3], to assess the shear bond strengths achieved using 37% phosphoric acid as a control. With the same bonding resin, shear bonds strengths of 7.1±4.4 MPa were found for the self-etching primer group, compared to 10.4±2.8 MPa for the control. The lower bond strengths achieved with the Prompt L-Pop were statistically significant, but the mean of 7.1 MPa was clinically acceptable[3].

Transbond Plus Self Etching Primer contains methacrylated phosphoric acid esters as the main ingredient, with no volatile organic compound content, and a pH value of 1.0[4]. The mechanism of action described by Cinader[5] in a manufacturer's publication. The phosphate group of the methacrylated phosphoric acid ester dissolves the calcium and removes it from the hydroxylappatite. Rather than being rinsed away, the calcium forms a complex with the phosphate group and is incorporated into the network when the primer polymerizes. Three processes serve to arrest the action of the acid in the material. First, the phosphate group forms a complex with the calcium of the hydroxylappatite (as with phosphoric acid). Secondly, the air burst serves to drive the solvent from the primer, increasing the viscosity of the material, slowing the transport of acid groups to the enamel surface. As the primer is light cured, and the monomers are polymerized, the transport of acid groups to the enamel surface is finalized.

The importance of rubbing-on of the self-etching primer and the airburst step is explained by the mechanism of action, since the first provides fresh etch, while the second then slows the etching, and removes the solvent which may form a barrier between the bonding resin and primer[6].

Miyazaki et al.[6] compared 3 (restorative) self-etching primer systems on bovine incisors, with varying drying times of 0, 2, 5, 10, 20, and 30 seconds. Significantly weaker shear bond strengths were obtained at shorter drying times for all systems. Etch morphology was also affected by different drying time; resin tag penetration was not clearly seen when the self-etching primer was not air dried, compared to intimately adapted resin tags being visible at 30 seconds of drying.

The variability in results obtained by different clinicians using the same products is established, especially when bonding/adhesive systems are used[7-9]. The success rates of pit and fissure sealants varied by as much as 24% at 3 year intervals between 2

operators[7]. Experience does not correlate with more successful results, as shown by the lack of correlation between shear bond strengths and years of experience when dental students and experienced dentists were introduced to a new dentin adhesive technique[9].

The purpose of this study was to compare the shear bond strengths obtained with the self etching primer, as compared to phosphoric acid etching for 15 seconds, using 2 common orthodontic adhesives. The variability between operators using the self etching technique, provided with manufacturer's instructions only, was also examined.

2.3 MATERIALS AND METHODS

Human Research Ethics Board approval was obtained for the study.

A power analysis was performed, using a power of 0.90, maximum difference of 3, and recently published self-etching primer values for standard deviation[3]. A minimum sample size of 65 for each study group was determined, with an objective of 71 teeth for each group, to account for possible exclusions and bond breakage in the apparatus. A pilot study was performed to refine the testing apparatus prior to study commencement.

Extracted human premolars were used for the study, stored in 10% formalin acetate solution for no longer than one month, then transferred to distilled water until use. The criteria for inclusion in the study were no previous chemical treatment, intact buccal surfaces that were un-restored and non-carious, and with sufficient root length to allow stable embedding in acrylic resin.

When 274 teeth were collected, they were randomly assigned to the various study groups, with 60 teeth being assigned to study inter-operator variability, and the remaining 214 to the shear bond strength comparison. The stainless steel orthodontic brackets were universal upper bicuspid type, Victory series (3M Unitek® Monrovia, USA), with a calculated surface area of 12.18 mm^2.

COMPARISON OF SHEAR BOND STRENGTHS

All teeth were cleaned with a slurry of pumice and prophy cup immediately prior to bonding. Three protocols were used with teeth bonded in random order. In Group A (N=71) the self-etching primer bubbles were pressed and folded back as per

manufacturer's instructions, and the material was rubbed into the enamel surface for 3 seconds with the applicator provided. After a 2 second air burst the brackets were bonded with Transbond XT resin. In Group B (N=72) the teeth were etched for 15 seconds with 35% w/w phosphoric acid etch (3M Unitek® Monrovia, USA), rinsed for 20 seconds, and air dried for 5 seconds. Transbond Primer was applied, followed by bracket bonding with Transbond XT resin. In Group C (N=71), each tooth was etched with 37% w/w phosphoric acid (Ormco® Orange, USA) for 15 seconds, rinsed for 20 seconds, and dried for 5 seconds prior to Ortho Solo™ (Ormco® Orange, USA) primer application. Brackets were bonded used Ormco Enlight® (Orange, USA) resin.

All brackets were subjected to a 400g force, as measured using a Dontrix gauge, and excess resin was removed. Brackets were light cured immediately after bonding, for 30 seconds in total; 10 seconds over the bracket face, and 20 seconds interproximally (10 seconds mesial, 10 seconds distal). A new Ortholux XT curing light (3M Unitek® Monrovia, USA) was used for curing, and was tested every 50 teeth to ensure consistent output greater than 400mW/cm^2.

Thermocycling was done using the technique described by Lee-Knight et al[10], between 2 water baths containing distilled water at 55° Celsius, and 5° Celsius. Seven hundred and fifty cycles were performed between these two temperatures, with dwell times of 30 seconds.

Following thermocycling, the teeth were embedded in pink orthodontic acrylic and mounted in square aluminium mounts. The teeth were embedded in the acrylic so that the bracket pad was parallel to the base of the holder, to ensure that the parallel application of force by the crosshead. The gingival tie wings of the brackets were a minimum of 3 mm away from the acrylic surface, to ensure that the bracket was freestanding.

Once mounted, the teeth were identified by number only, so that the method of bonding was unknown both during bond testing, and inspection for enamel fractures after debonding. Testing was done in random order for both portions of the study.

To test the shear load required to cause bracket removal, an MTS, Synergie 400 (MTS Systems Corporation, Eden Prairie, USA) machine was used, with a load cell of 500N and a measurement error of 0.003% of the full scale (1.5N). A blunted stainless

steel rod was fixed in the upper grip face, and a mounting jig in the lower grip face, into which the aluminium mount was placed. The crosshead speed was set at 2.5mm/minute, with the direction of force application being parallel to the bracket pad, in an occluso-gingival direction. The rod end was placed between the bracket tie-wings, and the bracket pad, as close to the tooth as possible. Figures I and II demonstrate the testing apparatus, in larger, and more detailed views.

Figure I: Study Apparatus

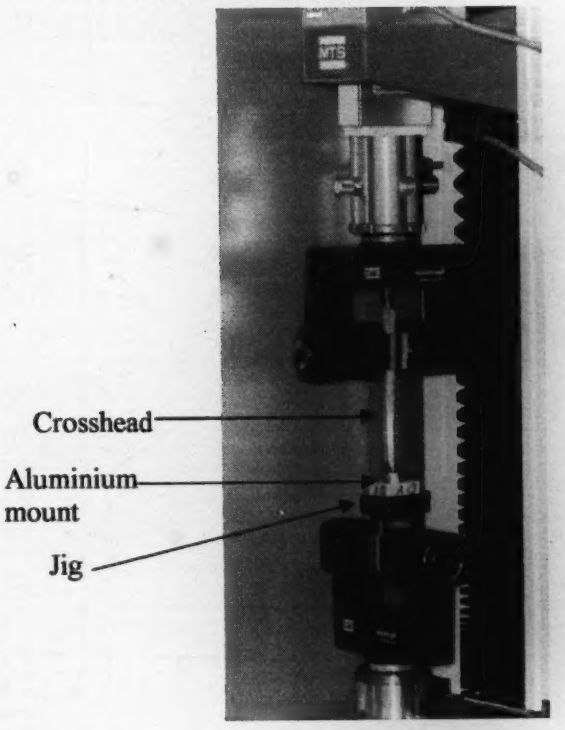
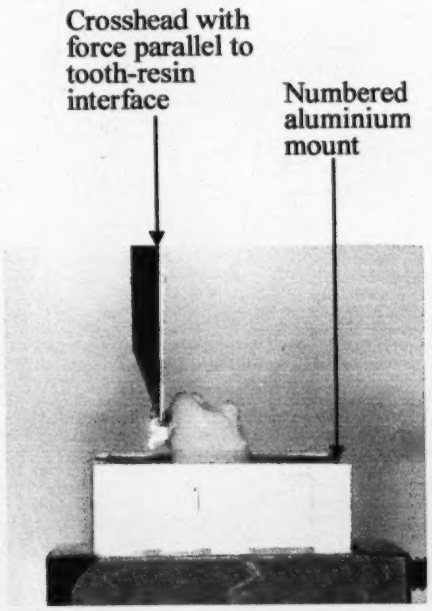


Figure II: Study Apparatus - Closer View



A computer connected to the MTS machine, using the Testworks™ program, (MTS Corporation, Eden Prairie, USA) controlled the crosshead speed, recording the peak load (Newtons) and peak stress (MPa) at bracket failure.

Each tooth in its aluminium holder was placed into the mounting jig, and the cross head was lowered into position between the bracket base and tie-wings, to be in contact with the bracket prior to beginning testing.

After debonding, each tooth was examined visually to ensure that crown integrity had remained sound, and to assess if enamel fractures were present.

The data obtained was subjected to one-way ANOVA. Descriptive statistics were calculated, and a post-hoc Bonferroni test was done to compare the specific mean values at a confidence level of 95%. Levene's test was used to compare standard deviations. Statistical analysis was done using SPSS software (SPSS, Chicago, US).

INTER-OPERATOR VARIABILITY

Three practicing orthodontists of varying ages and educational backgrounds agreed to take part, each bonding ≈20 teeth. An error by the study author accounts for the fact that one orthodontist bonded 21 teeth, while another bonded only 19.

Each operator was provided with identical written, diagrammatic manufacturer's instructions for use. No additional instructions were given, except to tell each operator to bond the teeth as he/she would in their office.

The buccal surface of the premolars was cleaned with a pumice slurry and prophy cup, and the teeth were embedded in Styrofoam slabs, with the crowns exposed. The teeth were then given to the orthodontist for bonding.

Each of the 3 orthodontists bonded ≈10 teeth using the Transbond Plus self-etching primer, and ≈10 teeth with 35% phosphoric acid. The operators chose technique order, and were responsible for etching and priming, bracket placement on the tooth, and excess resin removal. All brackets were loaded with Transbond XT resin by the author. When brackets were placed on 10 teeth using one technique, the study author performed the light curing step for 30 seconds.

When all teeth were bonded, they were stored overnight in a distilled water bath at 37°C until the 750 cycles of thermocycling were performed. Following thermal cycling, the teeth were embedded in acrylic, following the same procedures previously described. Teeth were identified by number only, and were tested in random order.

Teeth were placed in the testing apparatus ensuring that the force application was parallel to the bracket pad-tooth interface. After each bracket was de-bonded, it was visually examined for enamel fractures and crown integrity

The data obtained was subjected to one-way ANOVA and two-way ANOVA, with various grouping of data by operator, and by technique. Enamel fracture rates were analysed by a normal test and confidence interval of two proportions, and student's T test. The confidence level was 95%; statistical analysis was done using SPSS software (SPSS, Chicago, US).

2.4 RESULTS

SHEAR BOND STRENGTH TESTING

Of the 214 teeth included this portion of the study, 12 were debonded in error during testing apparatus set-up, and were discarded. During testing, 1 tooth fractured at the margin of an existing restoration (MOD), without debonding the bracket. This value was excluded from statistical analysis. No teeth were excluded in the inter-operator variability portion of the study.

Enamel fractures if present, were noted upon visual inspection immediately after the specimens were removed from the testing apparatus. All fractures were limited to the enamel, and were located immediately beneath the bracket pad (bonded area).

The descriptive statistics for the shear bond strength analysis portion of the study are presented in Table I, and enamel fracture rates in Table II.

Table I: Shear Bond Strengths by study group

Study Group Tested	Sample Size	Mean Bond Strength (MPa)	Standard Deviation	Range (MPa)
Self etching primer + Transbond XT	66	7.5	4.2	0.8 –18.8
35% phosphoric acid + Transbond XT	70	9.8*	4.2	2.0 – 22.0
37% phosphoric acid + Enlight	65	7.3	3.9	1.8 – 19.4

* denotes significantly larger than other 2 groups, $p<0.05$

Table II: Enamel Fracture Rates by study group

Study Group	Sample Size	Within Enamel Fractures	% Enamel Fractures
Self etching primer + Transbond XT	66	2	3%
35% phosphoric acid + Transbond XT	70	7	*10%
37% phosphoric acid + Enlight	65	0	0%

* denotes significantly greater than Enlight group only, $p<0.05$

Results demonstrated significantly higher bond strengths when teeth were bonded with 35% phosphoric acid and Transbond XT resin, than with self etching primer and Transbond XT ($p=0.004$), or phosphoric acid + Enlight ($p=0.002$) groups. The shear bond strengths of the self-etching primer group were not significantly different than those etched with 37% phosphoric acid + Enlight resin ($p=0.99$).

The standard deviations in the 3 methods used were not significantly different ($p=0.748$), ranging from 3.9 for the Enlight group, to 4.2 for the self-etching primer group. There was a wide range in values for all groups.

The 10% enamel fracture rate of the phosphoric acid etch + Transbond XT group, was significantly higher than the Enlight bonded group ($p=0.005$), but was not significantly higher than the self etching primer enamel fracture rate of 3% ($p=0.094$). There was no difference in enamel fracture rates between the Enlight resin and self etching primer groups ($p=0.151$).

The mean bond strength of teeth where enamel had fractured with debonding (15.5MPa) was significantly higher ($p=0.001$) that the mean bond strength of teeth that had not fractured (7.9 MPa). The variance in both groups was the same ($p=0.322$).

INTER-OPERATOR VARIABILITY

One-way ANOVA was done to determine the differences between operators. Shear bond strength values are shown in Table III, and significance levels in Table IV.

Table III: Inter-operator variability in shear bond strengths

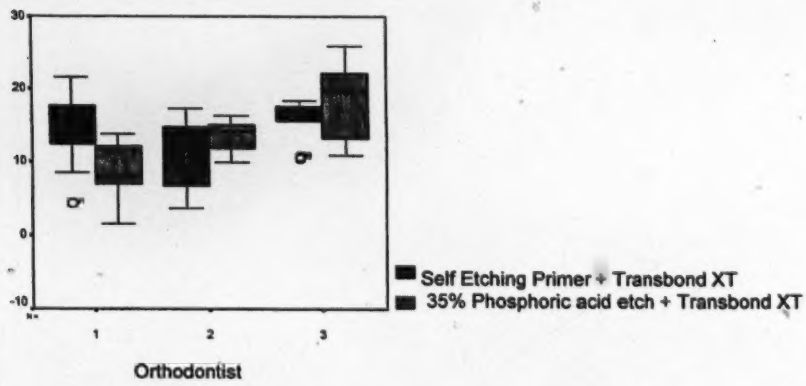
Operator	Etching Technique	Sample Size	Mean Shear Bond Strength (MPa)	Standard Deviation	Range
Orthodontist #1 (O1)	Self Etching Primer	11	14.4	5.0	4.4-21.6
	35% phosphoric acid	10	8.4	3.6	1.5-13.8
Orthodontist #2 (O2)	Self Etching Primer	10	10.6	4.6	3.7-17.3
	35% phosphoric acid	10	13.6	2.1	10.0-16.3
Orthodontist #3 (03)	Self Etching Primer	9	15.7	3.0	10.5-20.5
	35% phosphoric acid	10	18.6	5.4	10.9-25.9

Table IV: Inter-operator Shear Bond Strength Significance Levels

VARIABLE 1	VARIABLE 2	FINDING	P VALUE
Ortho 1: Self Etching Primer	Ortho 1: Phosphoric acid etch	SEP > PA	p=0.006
Ortho 2: Self Etching Primer	Ortho 2: Phosphoric acid etch	SEP = PA	p=0.079
Ortho 3: Self Etching Primer	Ortho 3: Phosphoric acid etch	SEP = PA	p=0.171
Self Etching Primer:			
Orthodontist 1	Orthodontist 2	O1=O2	p=0.155
Orthodontist 1	Orthodontist 3	O1=O3	p=0.999
Orthodontist 2	Orthodontist 3	O2=O3	p=0.051
Phosphoric Acid Etch:			
Orthodontist 1	Orthodontist 2	O1<O2	p=0.021
Orthodontist 1	Orthodontist 3	O1<O3	p=0.001
Orthodontist 2	Orthodontist 3	O2<O3	p=0.027

When the bond strengths of the three operators were grouped, no significant difference existed between etching methods (p=0.992), with means of 13.6 MPa for the self-etching primer group, and 13.53 MPa for the phosphoric acid etch group. When the data was split both by operator and by method, significant differences in mean shear bond strength were found. Figure III demonstrates the bond strengths achieved by different operators.

Figure III:Mean Bond Strength Values of Three Orthodontists



Within operators, both Orthodontists 2 and 3 had higher bond strength values for the phosphoric acid etching group than for the self-etching primer group, however this difference was not significant ($p=0.079$ and 0.171). The opposite was true of Orthodontist 1, who obtained significantly higher bond strengths ($p=0.006$) with the self-etching primer than with phosphoric acid (14.4 MPa ± 5.0, and 8.5 ± 3.6 respectively). These opposing trends between operators camouflaged bond strength differences when the different etching techniques were compared overall.

Operator 3 achieved significantly higher bond strength values than did Operators 1 and 2, when using the phosphoric acid etch technique ($p<0.05$ and $p=0.027$), however when the self-etching primer was used, no significant differences were found between the 3 orthodontists.

In the 60 teeth bonded by the 3 operators, 4 enamel fractures (13.3%) occurred in the self etching primer group, while 5 enamel fractures occurred in the phosphoric acid etched group (16.7%). These values are not significantly different ($p=0.717$). The mean shear bond strength of teeth with enamel fractures (16.7MPa) was significantly higher ($p=0.016$) than the value for those without enamel fractures (12.7MPa). The variance in both groups was the same ($p=0.602$).

2.5 DISCUSSION

The "artificial" setting of any in-vitro study is its main limitation. Teeth undergoing orthodontic treatment are not subjected exclusively to pure shear forces, nor are they bonded extraorally, and are immersed in saliva, not distilled water.

In an attempt to quantify the difference between bond strengths measured in-vitro and those achieved in vivo, a quantitative debonding device was used by Pickett et al[11]. The brackets and resin were the same as in the present study. The values obtained by the device in-vitro were significantly different than the values obtained in-vivo at the completion of orthodontic treatment. The mean bond strengths recorded in vitro, as measured by a Universal testing machine and debonding device were 11.0 MPa and 12.8 MPa respectively, while the mean value obtained in vivo was significantly lower at 5.4 MPa.

The in-vivo value in Pickett et al.'s study was after completion of orthodontic treatment, so that the shear bond strength may have degraded over time, with intra oral exposure to wide ranges of temperature, pH, and occlusal forces. Nevertheless, a large difference in values existed between the laboratory and clinical findings, suggesting that in-vitro bonding study results need to be substantiated in clinical trials.

This need to substantiate in-vitro testing with clinical trials was also demonstrated by Sunna et al, where clinical failure rates were found to have no correlation with the research group's ex-vivo shear bond strengths[12].

Bond study findings are reported as bond strength values, in units of MegaPascals, calculated by dividing the peak load at which a orthodontic bond fails (Newtons) by the surface area of the bracket (mm^2). The appropriateness of this measure is questioned by Katona[13], since dividing by the area yields average stress. Finite element model calculations have shown that stresses at the bracket-adhesive-tooth interface are not uniform, and that they are dependent on the method of force application (tensile, shear/peel). As a consequence, an average stress value (MPa) is not the best measure of outcome[14]. Finite element model computations also show that stress distribution within the adhesive (resin) layer is mode dependent[13], such that the loading method (tension, shear) influences the relative strength measures. In theory, tensile force

application could show one type of bond one being stronger than another, where shear/peel testing would conclude the opposite[13]. The comparability of the values obtained from bonding studies using different loading methods is then brought into question.

Shear Bond Strength Comparisons

The mean shear bond strength values in this study are very similar to those of Bishara et al[3], who examined Prompt L-Pop as the self-etching primer, using a somewhat different study protocol. The time of application of the self etching primer in their study was 20 seconds, as per Prompt L-Pop manufacturer's instructions. The Bishara study used the same premolar bracket, on extracted molars, after having been stored in 1% thymol, using a 300g compressive force, and without thermocycling. It is possible that these differences in technique may have negated each other to yield comparable values between the two studies. Alternately, the variables may not affect bond strengths to any large degree.

Self etching primer values measured in this study were comparable to those reported in previous studies using phosphoric acid and other common orthodontic adhesives[15 16].

The enamel acid etch pattern of the similar Prompt L-Pop self etching primer has been examined by scanning electron micrography, demonstrating consistently increased microporosity, 0.8μm etch depth, and a hybrid layer comparable to that of phosphoric acid etching[17]. The same study found bond strengths to be significantly weaker when the same bonding resin and phosphoric acid was used[17], supporting the findings of our study.

The standard deviation of bond values obtained using the 3 techniques was large, being approximately 50% of the mean shear bond strength value. The variation in bond values was however, consistent within the 3 groups. Bishara confirmed this finding of wide variation in bond strength with self etching primer, with a range of 6.4-19.1 MPa for Prompt L-Pop[3]. Wide variations in bond values are common in the literature; ranges of 7.0-31.7 MPa for phosphoric acid etch + Marathon® light cure resin were found by Blight and Lynch[18]. In contrast, Owens and Miller compared Transbond XT and Enlight resins, found a smaller range of values; 2.5-11.7 MPa and 3.3-7.1 MPa respectively[16].

The wide range of values obtained in both study sections are concerning, especially in a clinical setting. While there is no scientifically determined ideal bond strength range, there must be a value below which brackets will fail with normal intra-oral forces. Rather than using mean bond strength, perhaps a better measure of a material's value is the proportion of bonds that are above the threshold value. If a large proportion of values are at the low end of the distribution, it can be inferred that a greater number of bonds will have strengths below the critical value. Future research to determine the minimum bond strength value, as well as the proportion of values that fall above or below it for any given material, would greatly improve the validity of conclusions drawn from bonding studies.

Regardless of the bonding material used, a range in bond strengths will result. Several factors that may have contributed the variability in this study include varying levels of fluoride exposure, bonding of all premolars with an upper first bicuspid bond, and differences in buccal surface adaptation of the brackets.

The mean bond strengths between the 2 parts of the study were different, with the three operators obtaining higher bond strengths than those achieved by the study author. In the first part of the study, a 400gram force was applied to seat each bracket, in an effort to reduce adhesive thickness differences, minimizing one source of variability. The second portion of the study's goal was to mimic the clinical setting, so that each orthodontist seated the bracket with the force he/she felt appropriate. Differences in adhesive thickness between study sections may account for the differences in mean shear bond strength.

In the first section of the study, the phosphoric acid + Transbond resin group had a significantly higher rate of enamel fracture (10%) than the other 2 groups, as well as having the highest mean bond strength. Teeth with enamel fractures were also found to have higher mean bond strengths as a group when compared to non-fractured teeth in both portions of the study.

Enamel fracture rates in the second portion of the study were not significantly different ($p=0.717$) for the self etching primer (13.3%) and phosphoric acid etch (16.7%) groups, nor were the mean shear bond strengths ($p=0.980$). The mean bond strength of fractured teeth in this case, was the same ($p=0.602$) as non-fractured teeth.

The method in which brackets are removed at the termination of orthodontic treatment is not analogous to the study testing apparatus. This elevated level of enamel fracture using the materials in question has not specifically been reported in the literature, although enamel fractures have been reported with in-vitro specimens at bond strengths of 9.7MPa[19]. The enamel fracture rates of teeth bonded by the three orthodontists were also high, and no difference in fracture rates existed between etching techniques.

The bracket debonding method in the study (pure shear force, no archwire) may have contributed to the high enamel fracture rate, as well as the formalin storage medium. Formalin was chosen for its antibacterial activity, but formalin also serves as a fixative, causing protein cross-linking. Dentin is nearly 20% protein[20], and it since many of the premolars in this study had incomplete root formation, the open apex allowed the formalin to travel into the pulp chamber, dentinal tubules and dentin, causing protein denaturing. Formalin has also been shown to cause a rapid dehydration of dentin[21], causing it to become more brittle. The combined change in the dentin substructure affects the surrounding enamel, making it more prone to fracture. This increased enamel fracture rate is seen clinically in conditions where the dentin substrate is weakened, as in dentinogenesis imperfecta[22]. The high enamel fracture rates in the study should not considered evidence of a clinical problem, since they are likely the result of in vitro study conditions.

Inter-Operator Variability

The effect of operator variability on the performance of the dentin adhesives (in vitro) was large [8 9]. In one published study when 5 experienced general dentists were provided with written and verbal instructions regarding the dentin bonding technique, only one dentist performed the technique exactly as described by the manufacturer[8]. In another study where dental students were included, no correlation between the quality of the bond achieved, and the experience of the operator could be found[9].

The operators in the present study followed the manufacturer's instructions to varying degrees. No verbal instructions were provided for either technique, and operators were instructed to bond the teeth as they would in their office, ignoring the presence of the study coordinator.

Orthodontist 1 followed the manufacturer's instructions on the use of the self-etching primer exactly, while the others incorporated technique modifications such as omitting the air-burst step, and brushing-on the material rather than rubbing. The three operators also differed in their phosphoric acid etch technique, with the most obvious differences being in etch application time, and rinsing time. No operator following the manufacturer's instructions exactly for the phosphoric acid etch technique.

Operator 1 obtained significantly higher bond strength values with the self-etching primer than with the phosphoric acid etching group, in direct contrast to Operators 2 and 3, who had higher bond strengths with the phosphoric acid etched teeth.

Orthodontist 1 followed the manufacturers written instructions precisely for the self etching primer, and was generally unfamiliar with the technique before the study. The other two operators were familiar with the material and were using it in clinical practice.

Familiarity with the product seemed to predispose to the drift away from manufacturer's instructions, for both etching techniques. None of the operators exactly followed the manufacturer's instructions for phosphoric acid etching, while 0Orthodontist 3 following the instructions most closely.

When decreasing the number of steps and eliminating required materials, it is widely assumed that the bonding process will become more reliable. This hypothesis was shown true, however the technique modifications in the self etching primer technique did affect the ranking of materials.

Finger and Balkenhol have suggested that clinicians may not be sufficiently aware that basic rules of application change with the introduction of new generations of bonding materials[8]. The ramifications of introducing a "minor" change in the manufacturer's instructions may not be fully realized by the operators using the new material. On the contrary, with the Transbond Plus Self Etching Primer, technique modifications did not affect the resulting bond strengths.

A difference in material ranking was found between operators, however it was not due to differences in the self etching primer group. Rather, the phosphoric acid etch values varied widely according to the operator, resulting in Orthodontist 1 having higher

mean bond strength for the self etching primer group simply because of the low mean phosphoric acid etch bond strength.

So although decreasing the number of steps in the bonding process by combining the etching, rinsing and priming steps into one may make the technique more efficient, it does not seem to make the bonding of an orthodontic bracket to enamel any less prone to technique modifications. The technique modifications did not adversely affect bond strengths when using the self etching primer, implying that Transbond Self Etching Primer is less technique sensitive than conventional phosphoric acid etching.

2.6 CONCLUSIONS

1. Shear bond strength values of teeth bonded using Transbond Plus Self Etching Primer were significantly lower than those obtained using 35% phosphoric acid etch and the same bond resin (Transbond XT).
2. Shear bond strengths of teeth bonded using Transbond Plus Self Etching Primer were not significantly different than the shear bond strengths of teeth bonded using 37% phosphoric acid etch and Enlight bonding resin.
3. The variability in shear bond strengths achieved using self-etching primer and phosphoric acid etch techniques, were not significantly different, when 2 bonding resins (Transbond XT, and Enlight) were used.
4. Inter-operator variability between 3 practicing orthodontist was large:
    a. Significantly different shear bond strength values resulted from the 3 operators using the phosphoric acid etch technique.
    b. The ranking of shear bond strength values differed by operator, with 2 operators having significantly higher bond strengths using the phosphoric acid etch technique, and one operator having significantly higher values using the self-etching primer technique.

5. Decreasing the number of steps required to bond an orthodontic bracket, using a self-etching primer does not appear to adversely affect the bond strength, nor does it make a technique less likely to be modified by operators.
6. The mean bond strength values obtained by 3 orthodontists using the self etching primer, including technique modifications, were not significantly different, suggesting that the material is less technique sensitive than conventional phosphoric acid etching.

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DISCUSSION

3.1 STUDY DESIGN LIMITATIONS

Many authors have questioned the in-vivo applicability of in-vitro testing of bonding systems[1-3] both for dentin and enamel, in restorative and orthodontic systems.

When dentin bonding system testing was examined in the context of available clinical knowledge, in-vitro dentin bond strength tests were found to be unreliable enough to warrant using clinically based evidence when selecting bonding agents [3]. Finger also concluded that "bond strength figures of different sources are not readily comparable", and are only a "roughly discriminating parameter" correlating poorly with other in-vitro tests[4].

In 1990, a task group from the Accredited Standards Committee examined the clinical relevance of composite resin restorative material studies[5]. Their published report emphasized the clinical inapplicability of most in-vitro study methodologies. The ASC report called for standardization of testing protocols, before any comparisons of in-vitro studies from different research groups could be made.

In a parallel effort to standardise in-vitro bonding studies, in 1994 the ISO (International Organization for Standardization) published a report describing the criteria of a specific study protocol to be used[6]. Design protocols were specific, shear loads were to be tested with a crosshead speed of 0.5mm/min, storage of teeth in water at 37°C, with short term (24 hours), long term (6 months) and thermocycling (500 cycles, from 5°-55°C) protocols[6]. This protocol has not received wide acceptance and few, if any, published orthodontic adhesive studies have followed the policy set out by the ISO.

There are several design and protocol limitations in the present study, which if possible, should be addressed in further studies.

Studies have shown that different teeth do not etch (or bond) with the same success, with second bicuspids often showing lower bond strengths in vitro[7] and clinically[8], with maxillary second bicuspids showing the lowest bond strength[7]. Scanning electron micrography has shown that aprismatic enamel increases further posteriorly in the mouth[9], and that the ability to etch enamel decreases significantly with a more posterior location as well[10].

According to Oilo[11], there are 3 main factors which have a significant influence on the results of in-vitro testing besides the material itself; the test method (load type), the quality of the substrate, and the storage conditions of the specimens prior to testing.

In this study, no distinction made for the collection of first and second bicuspids, simply because of the difficulty in obtaining sufficient numbers of teeth. Ideally, a study should include only one specific type of tooth if tooth type variances are to be avoided, as suggested by Hobson et al[7]. The random distribution of teeth to the study groups normalized this variation, but the range of tooth certainly contributed to the large range in bond strengths.

The largest obstacle in this study was the collection of a sufficient number of appropriate teeth. Obtaining a large supply of erupted, relatively caries-free teeth of one type, such as bicuspids, is difficult, which is presumably the reason for studies using bovine teeth, or (impacted) third molars. The collection of teeth for this study was lengthy process taking place over a period of 12 months. For that reason, included teeth had variable storage times before testing. Teeth did not remain stored in formalin for greater than one month before being transferred into distilled water, but the time in distilled varied. If the availability of teeth was not such problem, relatively "fresh" teeth could be eliminating a possible confounding variable.

The teeth were also not controlled for fluoride content, as this would have required a history of residence in the Edmonton area for inclusion, with this information not being available in the study's collection process.

The study's random assignment of teeth to study groups minimized the effects of tooth type and anatomy, storage time, and fluoride content. These variables did however, contribute to the large variation in bond strengths found in all study groups.

The thermal cycling regime of 750 cycles used in the study was chosen mainly for the purpose of practicality. The thermocycling was done manually, since a programmable machine was not available. When done manually, regimes with short (3-5 seconds) dwell times, numerous temperature changes, and 10,000's cycles, are simply not feasible.

The storage conditions in this study may have contributed to the high enamel fracture rates found. A long storage time in distilled water, as well as microfractures in

enamel created during the extraction process, could both contribute to enamel fractures during mechanical debonding. The storage of teeth in 10% neutral buffered formalin for prior to being transferred to distilled water may also have contributed to the high fracture rate. The open apex of many adolescent premolars provided a conduit for formalin to travel to the pulp chamber, odontoblasts and dentinal processes, extending at least one third of the dentin thickness[12]. The fixative action of formalin crosslinks proteins, altering the structural composition of dentin in stored specimens. Since dentin provides the substructure for enamel, when it becomes more fragile with dehydration[13], and protein changes, the enamel is more prone to fracture.

The way in which the data from bond strength studies is analyzed statistically can also affect the outcome, and conclusions drawn from the data. When Eliades[1] subjected the same data set to a one way analysis of variance, a Tukey multiple range test and a Duncan test, different results were obtained with the pairwise multiple comparison tests. The Duncan test showed more significant differences between different study groups than did the Tukey test.

This study used the Bonferroni post hoc test, since study groups were not the same size. A Tukey test was done to confirm the significance findings only, so that those values were not reported.

Finite element model analysis of the resin-bracket-tooth system shows that despite the shortcomings, it is appropriate to compare bonding systems using differing loading methods, provided the testing protocols are meticulously constant, and that the average stress value (load/area) is not used[14]. This suggestion that loading modes could make results incomparable is not shared in the dental literature, where it is accepted that while shear testing may give higher values than tensile tests, the rank order remains the same[11].

Clinically, a strong and durable bond between the tooth and the orthodontic bracket is needed to transfer the forces from archwire and accessories, via the bracket, to the tooth. The need for a strong bond is balanced by the need for a bracket that can be removed (without difficulty) at the completion of treatment. In restorative dentistry materials with higher bond strengths are almost always an asset. In orthodontics, the bracket will be removed within 2-3 years of its placement, requiring a bond strength that is not so as to cause tooth damage.

Optimal bond strength then, would be strong enough to resist to debonding by intraoral forces such as occlusion, yet weak enough to allow easy and damage-free debonding at treatment completion.

Currently, no consensus exists as to this optimum strength, so that bonding studies such as this one, do not compare materials to a gold standard, but rather to other materials in clinical use. A valuable addition to the study of bonding materials would be the determination of this optimal strength range, so that more substantiated conclusions from in vitro bond studies could be made.

3.2 DESCRIPTION OF STRESS versus TIME CURVES

The range of shear bond strengths was large in both portions of the study. The load-time curve of all specimens was examined for differences in shape or trends. Specimens showed consistency in the load-time curves, regardless of the load at which the bracket failed, or the etching technique that was used. Teeth with enamel fractures also had the same load-time curve.

Representative bond strength–time curves are provided in Appendix 8.

3.3 SELF ETCHING PRIMER

The mechanism of action of Transbond Plus Self Etching Primer would suggest great importance for the rubbing-on of the self-etching primer and the airburst steps, since the former provides the etching process, while the latter not only slows the etching process but removes the solvent which may form a barrier between the bonding resin and primer[15]. The findings of this study suggest that the air burst step is critical, since one operator omitted the air drying completely, yet achieved a mean bond strength value that was not different than the other operators, who did provide the air burst.

Light curing of the monomers is the final step in acid neutralization, such that the self-etching primer is incompatible with chemical cure adhesives.

3.4 INTER-OPERATOR VARIABILITY

When eliminating materials, and decreasing the number of steps in the bonding process, it is widely assumed that the bonding process will become more reliable. This

concept was supported in the present study, since no differences in the mean bond strengths was found between operators with self etching primer, while significant differences existed between all operators when phosphoric acid was used.

New bonding methods and materials are introduced frequently, so that a lack of familiarity with a new material's specific instructions is a possible cause for technique failure. This was not the case in the present study, where although the operators already using the self-etching primer were more likely to introduce technique modifications, the bond strength values were not affected.

It would seem that when clinicians use a material or technique for some time, there is a slow "drift" away from the manufacturer's instructions, with the elimination of steps, or shortening the duration of each step. While the self etching primer in this study was unaffected by modifications, other materials or techniques, (such as phosphoric acid etching) may require periodic review of instructions to ensure optimal results.

3.6 RECOMMENDATIONS FOR FURTHER STUDY

1. The collection of teeth should encompass a larger group of contributors, so that a large sample of teeth can be collected from numerous sources, over a specific time period such as 3 months, minimizing storage time.
2. The use of a storage medium that more closely resembles saliva, for both storage, and thermal cycling. The osmolarity and pH values at a minimum should be similar.
3. Use of a mechanical thermocycling unit (Saskatoon for instance) to allow for a more comprehensive thermocycling protocol, more accurately depicting the thermal cycling a bracket is exposed to during the average 2-3 year orthodontic treatment.
4. Examination under light microscope magnification after debonding of bracket, to determine the ARI (Adhesive Remnant Index), and detect smaller enamel fractures.
5. Research aimed to quantify the ideal bond strength range, so that further bonding studies have a critical value against which new materials can be tested.
6. Studies that examine the proportion of bond values distributed above and below the critical bond strength value.

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Appendix 1: Human Research Ethics Board Approval
Page 1 of 2

February 15, 2002

Ms. Helen Grubisa
#605, 8920 – 100 St.
Edmontoin, AB
T6E 4Y8

Dear Ms. Grubisa,

Re: Bonding Study of Orthodontic Brackets Using Self-etching Primer.

Thank you for submitting the above study to the Health Research Ethics Board (B: Health Research). The board members appreciated the opportunity to learn of the research you are planning to conduct and to provide comments. The reviewers were pleased with your study as presented, and felt the study complied with the *University of Alberta Standards for the Protection of Human Research Participants, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and Health Information Act.*

If applicable, please note that the Health Research Ethics Board does not encompass authorization to access the patients, staff or resources of Capital Health, Caritas or other local health care institutions for research purposes. Enquiries regarding administrative approval requirements should be directed to the appropriate organization. (For Capital Health contact Shanie Maharaj, 407-6221; for Caritas, contact Diane Robinson, 930-5908).

Please find enclosed your letter of ethical approval for the above study. Please quote file number **B-160202-DENT** in any future correspondence with the ethics board. On behalf of the Health Research Ethics Board (B: Health Research), I wish you every success in your research endeavours.

Sincerely,

K Turpin

Karen Turpin
Administrative Assistant
Health Research Ethics Board (B: Health Research)

Health Research Ethics Board | biomedical research | health research

2J2.27 Walter Mackenzie Centre
University of Alberta, Edmonton, Alberta T6G 2B7
p.780.492.9724 f.780.492.7303
ethics@med.ualberta.ca

3-48 Corbett Hall, University of Alberta
Edmonton, Alberta T6G 2G4
p.780.492.0839 f.780.492.1626
ethics@www.rehabmed.ualberta.ca

UNIVERSITY OF ALBERTA HEALTH SCIENCES FACULTIES,
CAPITAL HEALTH AUTHORITY, AND CARITAS HEALTH GROUP

HEALTH RESEARCH ETHICS APPROVAL

Date:	February 2002
Name of Applicant:	Ms. Helen Grubisa
Organization:	University of Alberta
Department:	Graduate Studies; Dentistry
Name of Co-applicant:	Dr. Ken Glover
Organization:	University of Alberta
Department:	Dentistry
Project Title:	Bonding Study of Orthodontic Brackets Using Self-etching Primer

The Health Research Ethics Board (HREB) has reviewed the protocol for this project and found it to be acceptable within the limitations of human experimentation.

The deliberations of the HREB included all elements described in Section 50 of the *Health Information Act*, and found the study to be in compliance with all the applicable requirements of the Act. Due to the retrospective nature of the study, the HREB determined there to be no need to obtain written informed consent from the subjects.

The approval for the study as presented is valid for one year. It may be extended following completion of the yearly report form. Any proposed changes to the study must be submitted to the Health Research Ethics Board for approval. Written notification must be sent to the HREB when the project is complete or terminated.

Karen Tuzi for

Dr. Sharon Warren
Chair of the Health Research Ethics Board (B: Health Research)

File number: B-160202-DENT

Appendix 2:
SUPPLEMENTAL INFORMATION REGARDING TOOTH COLLECTON AND STUDY DESIGN

Extracted human premolars were used for the study, including maxillary, mandibular, first, and second premolars. Oral surgeon, and general dental offices took part in the collection of teeth in the Edmonton area, so that teeth would likely to have been exposed to similar quantities of fluoride.

Two collection "routes" were used for the tooth acquisition. The large majority (>75%) were collected from a group (oral surgery). Approximately 10-15% were obtained from orthodontic patients at the Graduate Orthodontic Clinic, University of Alberta . Patients of the clinic being referred for extraction of bicuspids were provided with a small jar, and an introduction letter, If desired, the patients could return the jar containing the extracted bicuspids, to receive remuneration of $1 per bicuspid.

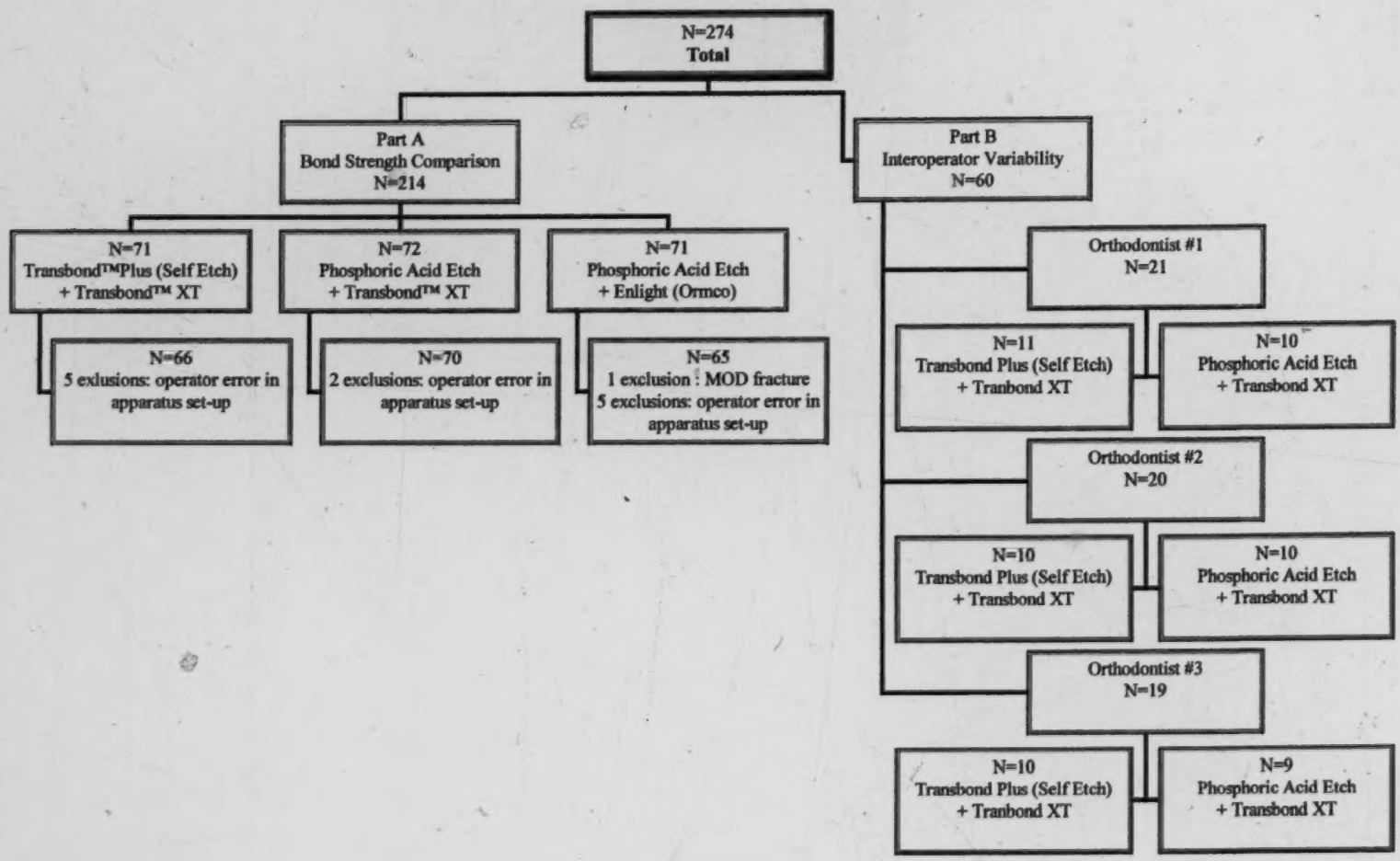
The teeth were cleaned thoroughly, first to remove gross debris and tissue remnants. Then, the tooth roots were scaled using a periodontal scaler (HuFriedy) to remove the remaining periodontal ligament on the root surface. Once cleaned, the teeth were replaced in the formalin solution for 24 hours, then transferred to distilled water for storage until study commencement.

Three study groups were involved, with each group using a different bonding/etching method.

STUDY GROUP	ETCH	PRIMER	BOND RESIN
A	Transbond™ Plus		Transbond™ XT
B	35% phosphoric acid (w/w)	Transbond™ XT	Transbond™ XT
C	37% phosphoric acid (w/w)	Ortho Solo™	Enlight®

All required materials were taken from the same lot numbers (Appendix 4), having been shipped less than one month prior to use. All bonding was done in the same clinic (University of Alberta, Graduate Orthodontic Clinic), using the same dental unit, on the same day. Water and oil-free air supplies were constant.

Appendix 3: Allocation of Teeth To Study Groups



Appendix 4: LOT NUMBERS OF MATERIALS USED IN STUDY

MATERIAL	SUPPLIER	LOT/BATCH NUMBER	EXPIRY DATE
10% buffered formalin acetate	Fisher Scientific	003064-24	2003-02
Acrylic Resin Powder	Dentsply Caulk	0911104	2004-02
Pink Acrylic Liquid	Dentsply Caulk	010410	2004-02
Transbond™Plus (self etching primer)	3M Unitek	116201	2003-04
Scotchbond 35% (w/w) Phosphoric Acid etch	3M Unitek	1WR	2004-06
Transbond™XT Primer	3M Unitek	1AN	
Transbond™XT Resin	3M Unitek	1CM	2004-07
Ormco® 37% (w/w) Phosphoric Acid	Ormco	1A2	2003-03
Ortho Solo™ Primer	Ormco	104272	
Ortho Enlight® Resin	Ormco	28710	2003-03

Appendix 5: Part A Raw Data

ID #	Method	Peak Load N	Peak Stress MPa
1	C	61.494	5
2	B	268.076	22
3	C	80.609	6.6
5	A	39.196	3.2
6	C	153.566	12.6
7	A	41.316	3.4
9	C	66.109	5.4
10	C	236.271	19.4
11	C	73.199	6
12	B	147.614	12.1
13	C	91.243	7.5
14	B	82.819	6.8
15	C	71.748	5.9
16	A	156.176	12.8
17	A	76.083	6.2
18	A	167.587	13.8
19	C	114.981	9.4
20	A	107.578	8.8
21	C	110.783	9.1
22	A	205.742	16.9
23	A	180.107	14.8
24	B	87.054	7.1
25	A	60.6	5
26	C	174.617	14.3
27	C	21.605	1.8
28	A	132.928	10.9
29	C	75.159	6.2
31	A	69.959	5.7
32	B	193.605	15.9
33	C	42.889	3.5
34	B	75.129	6.2
35	B	72.199	5.9
36	B	177.917	14.6
37	C	110.205	9
38	A	228.656	18.8
39	A	169.828	13.9
40	A	161.805	13.3
41	C	69.539	5.7
42	A	168.472	13.8
43	C	97.048	8
44	C	47.399	3.9
45	A	91.744	7.5
46	C	44.614	3.7
47	A	57.199	4.7
48	C	47.894	3.9
49	B	125.558	10.3
50	B	24.165	2
51	A	60.178	4.9
52	B	134.953	11.1

A= self etching primer + Transbond XT
B= 35% phosphoric acid + Transbond XT
C= 37% phosphoric acid + Enlight

53	C	118.643	9.7
54	C	24.025	2
55	A	58.819	4.8
56	B	87.356	7.2
57	C	61.839	5.1
58	C	55.455	4.6
59	C	94.334	7.7
60	C	61.139	5
61	A	94.908	7.8
62	B	95.345	7.8
63	B	41.587	3.4
64	C	100.474	8.2
65	A	43.619	3.6
66	C	73.229	6
67	C	176.125	14.5
68	B	180.382	14.8
69	B	139.653	11.5
71	C	59.544	4.9
72	A	79.062	6.5
73	C	128.521	10.6
74	B	88.969	7.3
75	A	45.239	3.7
76	C	204.582	16.8
77	C	111.473	9.2
78	B	149.944	12.3
79	A	67.414	5.5
80	B	84.276	6.9
81	B	110.743	9.1
82	B	130.288	10.7
83	B	80.854	6.6
84	C	65.744	5.4
85	C	22.89	1.9
86	A	86.704	7.1
87	C	21.635	1.8
88	B	102.219	8.4
89	A	146.805	12.1
90	B	77.059	6.3
91	C	125.653	10.3
93	A	180.401	14.8
94	A	11.605	1
95	C	41.094	3.4
96	B	148.893	12.2
97	A	86.504	7.1
98	B	163.125	13.4
99	B	61.236	5
100	B	87.594	7.2
103	B	89.466	7.3
104	A	58.044	4.8
105	A	44.829	3.7
106	C	121.468	10
107	A	66.514	5.5
108	A	112.471	9.2
109	B	126.453	10.4
110	C	34.034	2.8
111	C	21.665	1.8
112	B	211.807	17.4

113	C	130.658	10.7
114	A	54.309	4.5
115	B	128.493	10.5
116	C	72.874	6
117	A	54.484	4.5
118	A	101.578	8.3
119	C	70.8	5.8
120	A	118.913	9.8
121	A	33.328	2.7
122	B	68.434	5.6
123	A	11.21	0.9
124	B	118.233	9.7
126	C	50.034	4.1
127	B	222.956	18.3
128	C	72.166	5.9
130	A	124.005	10.2
131	A	103.729	8.5
132	B	133.163	10.9
133	A	109.928	9
134	C	38.096	3.1
135	B	180.877	14.8
136	C	184.91	15.2
137	B	146.896	12.1
138	B	258.606	21.2
139	C	56.329	4.6
140	B	46.584	3.8
141	B	91.369	7.5
142	B	125.329	10.3
143	B	147.593	12.1
144	A	10.326	0.8
145	B	96.164	7.9
146	A	13.83	1.1
147	B	167.431	13.7
148	B	125.638	10.3
149	C	139.427	11.4
150	B	134.728	11.1
151	B	78.856	6.5
152	B	163.892	13.5
153	C	125.928	10.3
154	A	108.759	8.9
155	C	118.633	9.7
156	A	125.738	10.3
157	A	74.637	6.1
158	B	101.747	8.4
159	B	46.579	3.8
160	B	94.284	7.7
162	B	119.188	9.8
163	B	42.957	3.5
164	A	69.766	5.7
165	A	49.378	4.1
166	C	74.117	6.1
167	B	38.624	3.2
168	A	78.134	6.4
169	B	142.873	11.7
170	B	190.472	15.6
171	C	58.214	4.8

172	A	42.428	3.5
173	C	74.759	6.1
174	A	92.609	7.6
175	B	102.098	8.4
176	B	98.71	8.1
177	C	117.618	9.7
178	C	146.961	12.1
179	B	96.533	7.9
180	C	90.014	7.4
181	C	96.558	7.9
182	B	55.945	4.6
183	A	39.339	3.2
184	B	113.163	9.3
185	B	59.875	4.9
186	C	33.238	2.7
187	A	156.578	12.9
188	C	56.582	4.6
189	A	75.698	6.2
190	B	184.223	15.1
192	A	63.424	5.2
193	A	133.893	11
194	B	97.398	8
195	B	72.534	6
197	A	59.033	4.8
198	B	112.423	9.2
199	C	105.564	8.7
200	A	47.932	3.9
201	B	152.238	12.5
202	C	130.848	10.7
204	B	124.902	10.3
205	A	186.627	15.3
203	A	113.938	9.4
206	C	130.783	10.7
207	A	43.559	3.6
208	B	189.762	15.6
209	A	71.404	5.9
210	A	129.063	10.6
211	C	129.993	10.7
212	C	24.98	2.1
213	A	113.768	9.3
214	A	35.382	2.9

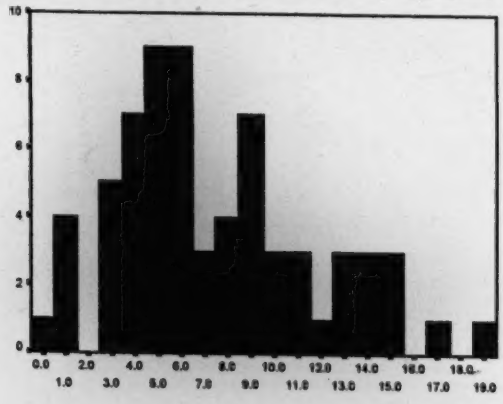
Appendix 6: Raw Data for Part B
Inter-operator Variability

Study Group	Peak Load N	Peak Stress MPa
1	173.282	14.2
5	249.897	20.5
3	136.348	11.2
1	208.697	17.1
3	76.059	6.2
4	144.508	11.9
1	234.888	19.3
5	210.122	17.3
4	188.607	15.5
6	133.279	10.9
6	169.159	13.9
2	107.423	8.8
5	225.816	18.5
3	119.413	9.8
4	165.745	13.6
2	95.628	7.9
4	126.644	10.4
4	180.01	14.8
5	189.697	15.6
1	150.703	12.4
1	263.231	21.6
4	183.369	15.1
1	207.057	17
3	206.207	16.9
6	261.251	21.4
2	148.768	12.2
3	210.721	17.3
6	315.877	25.9
5	216.619	17.8
5	131.141	10.8
1	164.122	13.5
2	147.405	12.1
4	163.498	13.4
5	200.701	16.5
1	151.693	12.5
6	270.121	22.2
6	162.307	13.3
3	139.367	11.4
4	181.955	14.9
2	91.169	7.5
1	53.628	4.4
2	85.389	7
5	127.783	10.5
6	236.65	19.4
2	103.703	8.5
2	65.738	5.4
3	45.005	3.7
1	225.691	18.5
5	199.642	16.4
4	198.557	16.3
3	180.232	14.8
5	214.802	17.6
2	168.512	13.8
6	159.728	13.1
2	18.71	1.5
4	122.293	10
6	303.167	24.9
3	94.084	7.7
3	81.139	6.7
1	103.888	8.5

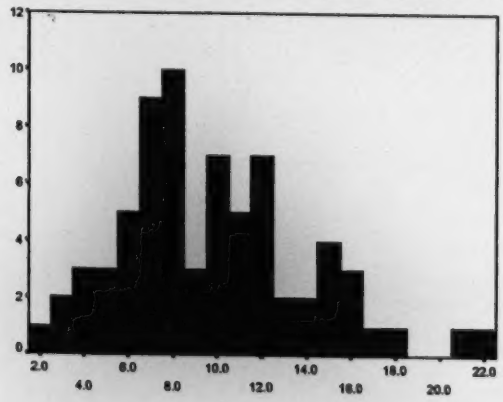
1= Orthodontist 1, self etching primer (SEP)
2= Orthodontist 1, 35% phosphoric acid (PA)
3= Orthodontist 2, SEP
4= Orthodontist 2, 35% PA
5= Orthodontist 3, SEP
6= Orthodontist 3, 35% PA

APPENDIX 7: Distribution of Shear Bond Strength (MPa) Values for:

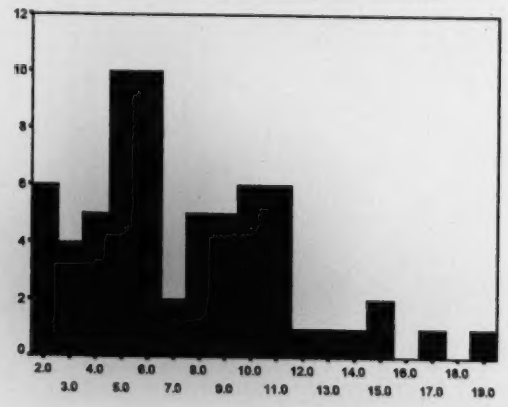
Self Etching Primer + Transbond XT resin



35% Phosphoric Acid + Transbond XT resin

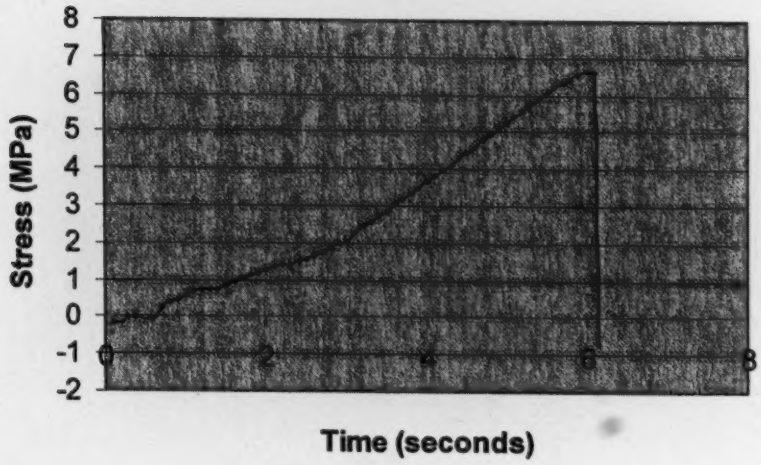


37% Phosphoric Acid + Enlight Resin

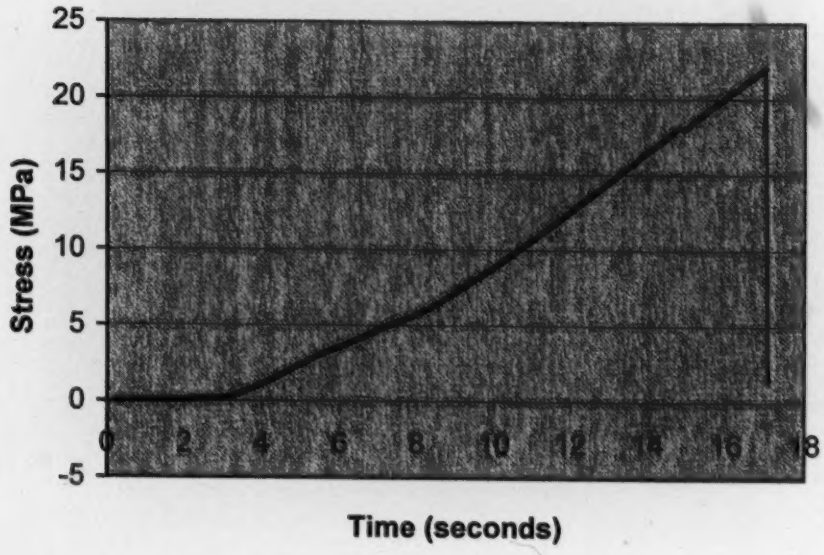


Appendix 8: CURVES OF STRESS VS TIME FOR VARIOUS SPECIMENS

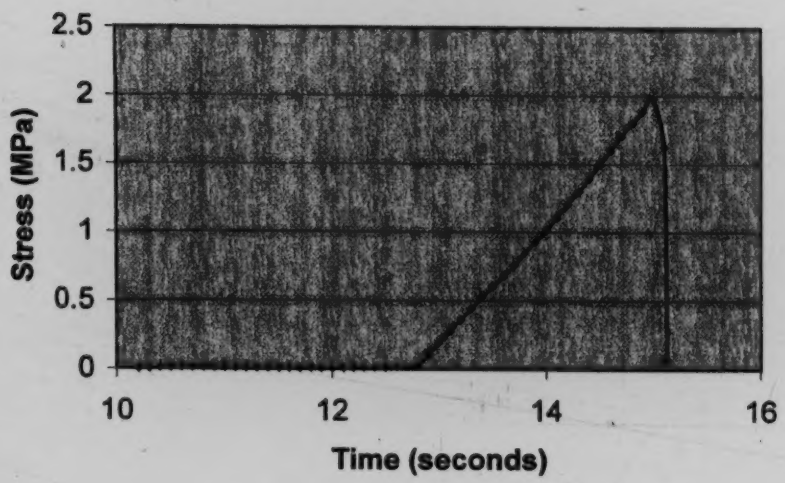
Stress Curve of Self Etching Primer Specimen:
Mean Value



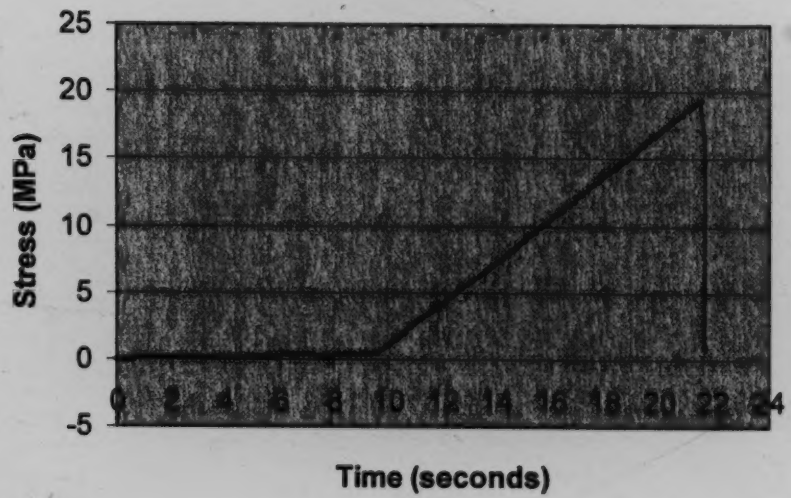
Stress Curve for Phosphoric acid + Transbond
Resin: Highest Bond Strength Value



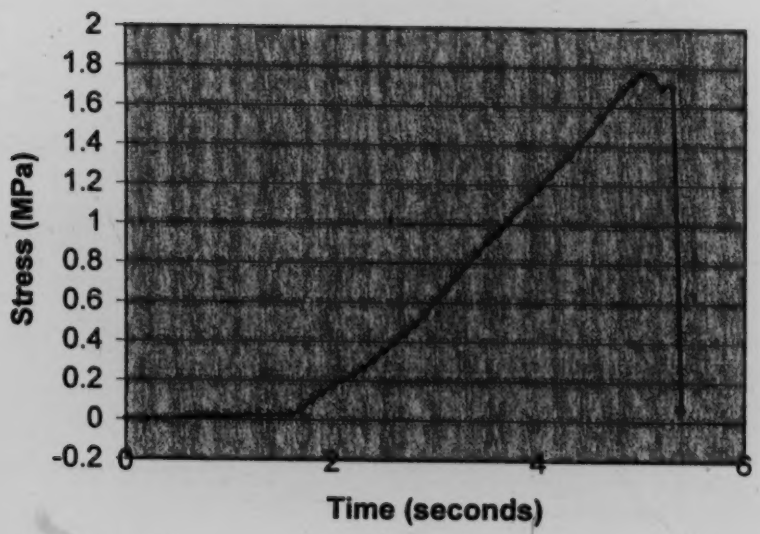
Stress Curve for Phosphoric Acid + Transbond Resin: Lowest Value



Stress Curve for Phosphoric Acid + Enlight Resin: Highest Value

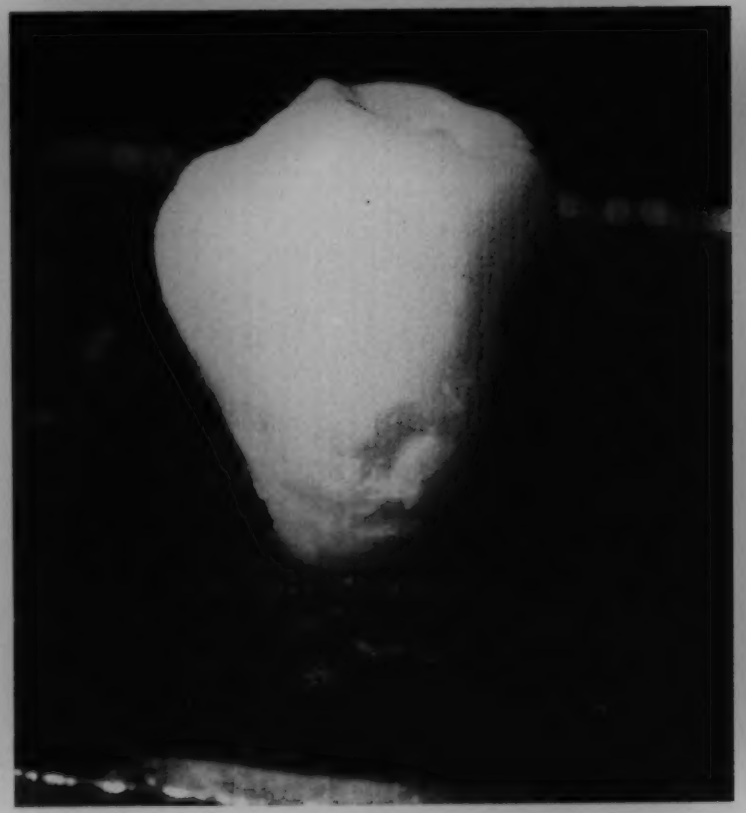


Stress Curve for Phosphoric Acid + Enlight
Resin: Lowest Value



APPENDIX 9: ENAMEL FRACTURES

Smallest Enamel Fracture



Largest Enamel Fracture